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REGULATORY ADR FOR A CONSENSUS VACCINE STANDARD

Avraham Snider

On November 4, 2021, the Occupational Safety and Health Administration (“OSHA”) issued an emergency temporary standard (“ETS”) mandating that businesses with over 100 employees ensure that their employees be vaccinated against COVID-19 or be tested weekly for the virus.¹ The temporary regulation set off a whirlwind of litigation from business groups and several state attorneys general.² The cases were consolidated and received different rulings from the Fifth and Sixth Circuits, leading the U.S. Supreme Court to step in.³ In a per curium opinion (“NFIB case”), the Supreme Court found that a statute on workplace hazards did not justify a mandate that would have required more than eighty million workers to be vaccinated against the coronavirus or be tested weekly.⁴ The Court also stressed the broad reach of the mandate. The majority opinion noted that Congress had not authorized the agency to create a mandate that “draws no distinctions based on industry or risk of exposure to COVID-19,”⁵ adding that it was “a significant encroachment into the lives—and health—of a vast number of employees.”⁶ However, the majority said that more tailored regulations may be lawful, given that “most lifeguards and linemen face the same regulations as do medics and meatpackers.”⁷

Following the Court’s decision, OSHA revoked the temporary standard but stated, “Although OSHA is withdrawing the Vaccination and Testing ETS as an enforceable emergency temporary standard, OSHA is not withdrawing the ETS to the extent that it serves as a proposed rule . . . or otherwise affect[s] the status of the notice-and-comment rulemaking commenced by the Vaccination and Testing ETS.”⁸ Presumably, this means that OSHA intends to proceed with a vaccine mandate as a permanent rule through its standard notice and comment rulemaking procedures.

Rulemaking involving controversial issues of public interest tends to garner a significant number of comments that the agency must address. Under the Administrative Procedures Act (“APA”), agencies must give the public the opportunity to offer their “data, views, or arguments” for the agencies’ consideration.⁹ When rules are challenged on judicial review, courts have required agencies to demonstrate that they have considered and responded to any comment that

¹ Lauren Hirsch, *U.S. Sets Jan. 4 Vaccination Deadline for Big Private Employers*, N.Y. TIMES (Nov. 12, 2021), <https://www.nytimes.com/2021/11/04/business/biden-vaccine-mandate-osha.html> [<https://perma.cc/9R7P-RLE5>].

² Charlie Savage, *Challenges to Workplace Vaccine Mandate Moved to Appeals Court in Cincinnati*, N.Y. TIMES (Nov. 16, 2021), <https://www.nytimes.com/2021/11/16/us/politics/biden-vaccine-mandate-osha-ohio.html> [<https://perma.cc/G7WC-33F6>].

³ Adam Liptak, *Supreme Court to Hold Special Hearing on Biden Vaccine Mandates*, N.Y. TIMES (Dec. 22, 2021), <https://www.nytimes.com/2021/12/22/us/politics/osha-vaccine-mandate-supreme-court.html> [<https://perma.cc/TUY7-GG25>].

⁴ Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab., Occupational Safety & Health Admin., 142 S.Ct. 661 (2022) (per curium).

⁵ *Id.* at 664.

⁶ *Id.* at 665.

⁷ *Id.* at 664.

⁸ *COVID-19 Vaccination and Testing; Emergency Temporary Standard* [Interim Rule Withdrawal, 87 Fed. Reg., at 3928–29], FED. REG. (Jan. 26, 2022), <https://www.federalregister.gov/documents/2022/01/26/2022-01532/covid-19-vaccination-and-testing-emergency-temporary-standard> [<https://perma.cc/A2HD-3D5K>].

⁹ 5 U.S.C. § 553.

raises a significant issue.¹⁰ With advances in technology and the movement of comments online in 2003,¹¹ controversial rules have garnered large numbers of comments, ranging from hundreds of thousands to millions.¹² While many of the comments are duplicative, fraudulent, or misidentified, the agency must still determine how to manage the multitude of responses.¹³ While there is no way of knowing how many comments the OSHA rule would receive, presumably, mass comment campaigns will be waged in an effort by opposing groups to prevent OSHA from regulating this hot button issue. This will likely delay the promulgation of the final rule and drain the agency's resources.

However, a form of regulatory ADR may help OSHA create a rule with direct input from business groups that would reduce the need for comments and prevent litigation over the agency's final rule. Negotiated rulemaking is the process by which an agency, with the assistance of one or more neutral advisers, assembles a committee of representatives of all affected interests to negotiate a proposed rule.¹⁴ The goal of the process is to reach a consensus on the text of a proposed rule that all parties can accept. The members of the negotiated rulemaking committee determine what factual information or other data are necessary for them to make a reasoned decision, develop and analyze the information, examine the legal and policy issues involved in the regulation, and reach a consensus on the recommendation to propose to the agency.¹⁵ Negotiated rulemaking has largely fallen out of vogue with federal agencies and has been rarely used in recent years, aside from when mandated by statute.¹⁶

The statute establishing the framework for negotiated rulemaking is the Negotiated Rulemaking Act ("NRA").¹⁷ The NRA does not require the use of negotiated rulemaking; rather, it clarifies agency authority and encourages agency use of the process, allowing each agency the choice of whether to employ it.¹⁸ Negotiated rulemaking supplements—not replaces—the notice and comment process. As opposed to drafting a rule and changing it in response to comments, negotiated rulemaking allows the regulated entities to assist in drafting the proposed rule and

¹⁰ *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to significant comments received during the period for public comment.").

¹¹ *About the eRulemaking Initiative*, REGULATIONS.GOV, <https://www.regulations.gov/about> [<https://perma.cc/LQG6-7ZE3>] (last visited Feb. 3, 2022).

¹² See e.g., Paul Hitlin, Kenneth Olmstead, & Skye Toor, *Public Comments to the Federal Communications Commission About Net Neutrality Contain Many Inaccuracies and Duplicates*, PEW RSCH. CTR. (Nov. 29, 2017), <https://www.pewresearch.org/internet/2017/11/29/public-comments-to-the-federal-communications-commission-about-net-neutrality-contain-many-inaccuracies-and-duplicates/> [<https://perma.cc/CU54-CLBN>]. When the U.S. Federal Communications Commission (FCC) considered regulations regarding net neutrality in 2014 and 2017, over twenty-one million comments were submitted. However, many of the comments were fraudulent and duplicative. For example, of the 21.7 million comments posted, 94% were submitted multiple times, and 57% of the comments were from either duplicate email addresses or temporary email addresses.

¹³ *Managing Mass, Computer-Generated, and Falsely Attributed Comments*, ADMIN. CONF. U.S. (June 30, 2021), <https://www.acus.gov/recommendation/managing-mass-computer-generated-and-falsely-attributed-comments> [<https://perma.cc/7MY6-AH2Y>].

¹⁴ Jeffrey S. Lubbers, *Achieving Policymaking Consensus: The (Unfortunate) Waning of Negotiated Rulemaking*, 49 S. TEX. L. REV. 987 (2008).

¹⁵ Philip J. Harter, *Assessing the Assessors: The Actual Performance of Negotiated Rulemaking*, 9 N.Y.U. ENV'T L. J. 32, 33 (2000).

¹⁶ See generally Lubbers, *supra* note 14.

¹⁷ See Negotiated Rulemaking Act, 5 U.S.C. §§ 561–71.

¹⁸ *Id.*; see also 5 U.S.C. § 561 ("Nothing in this subchapter should be construed as an attempt to limit innovation and experimentation with the negotiated rulemaking process or with other innovative rulemaking procedures otherwise authorized by law.").

participate in a presumably shorter comments process.¹⁹ In determining whether to engage in negotiated rulemaking, agencies consider the factors that generally lead to successful outcomes, such as whether there are a limited number of identifiable interests, whether there is a reasonable likelihood that a balanced representative committee can be convened, and whether there is a reasonable likelihood that the committee can arrive at a consensus.²⁰

Negotiated rulemaking is believed to save time and expense from the overall rulemaking process by initially bringing together groups representing disparate interests, so that concerns can be voiced before a rule is developed.²¹ The early discussions aim to reduce the number of comments that agencies receive on the back end, hopefully decreasing the agency's workload in responding to comments.²² Importantly, for controversial rules, getting the affected parties on board may be very helpful in preventing the agency from having to deal with a cascade of comments. Negotiated rulemaking also reduces expensive litigation over the final rule by having stakeholders play a role in developing the rule.²³

However, serious roadblocks stand in the way of a successfully negotiated vaccine rule. First, there is a multitude of affected parties, each of whom will want a seat at the negotiating table, making it exceedingly difficult to create a balanced, manageable committee to negotiate the proposed rule. The OSHA temporary standard was challenged in every judicial circuit, totaling hundreds of litigants.²⁴ The case that the 6th Circuit heard was a consolidation of thirty-four cases from across the country, often with multiple parties making the challenge.²⁵ Additionally, several Republican-led states filed lawsuits challenging the rule.²⁶ This multitude of litigants only reflects the plaintiff's side of the dispute. Considering the other side, there would seem to be many parties in favor of creating a vaccine rule, such as labor unions.²⁷ Such groups would likely want to be included in the rulemaking committee to ensure their views are considered. These broad and deeply held interests will, no doubt, make it very difficult to form a balanced committee that would be small enough to create a workable environment for negotiations.

Negotiated rulemaking is typically understood to work best when there are a limited number of parties involved; this is evident in the NRA, which recommends limiting the number of participants in the rulemaking committee to twenty-five members.²⁸ Given the large number of parties that would be affected by the OSHA rule, it would seem almost impossible to strike the right balance between ensuring that the parties' interests are fairly represented and creating a workable negotiating environment.

¹⁹ Lubbers, *supra* note 14, at 991.

²⁰ 5 U.S.C. §§ 563a (1)–(6).

²¹ Philip J. Harter, *Negotiating Regulations: A Cure for the Malaise?*, 71 GEO. L. J. 1, 28–30 (1982).

²² Julia Kobick, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food and Drug Administration?*, 65 FOOD & DRUG L. J. 425, 432 (2010).

²³ Harter, *supra* note 15, at 51.

²⁴ Notice of Filing with the Judicial Panel on Multidistrict Litigation, *BST Holdings v. OSHA*, Docket No. 21-60845 (5th Cir. Nov 05, 2021), <https://pacer-documents.s3.amazonaws.com/200/21-60845/00506094112.pdf>.

²⁵ Savage, *supra* note 2.

²⁶ Robert Iafolla, *Covid Shot-or-Test Rule Opponents Press Supreme Court for Stay*, BLOOMBERG L. (Jan. 3, 2022, 1:11 PM), <https://news.bloomberglaw.com/daily-labor-report/covid-shot-or-test-rule-opponents-press-supreme-court-for-stay> [<https://perma.cc/84R6-V3ES>].

²⁷ Spencer Kimball, *Labor Unions Sue Biden Administration to Expand Covid Vaccine Mandates and Cover Smaller Businesses*, CNBC (Nov. 15, 2021, 12:05 PM), <https://www.cnbc.com/2021/11/15/biden-vaccine-mandate-unions-sue-to-include-more-covid-protections.html> [<https://perma.cc/65Y7-2DKP>].

²⁸ 5 U.S.C. § 565(b).

Another reason OSHA is unlikely to use negotiated rulemaking is the Supreme Court's holding that struck down the temporary standard—this has given business groups the momentum to challenge a future rule, and it has also resulted in there being less of an incentive for the affected parties to cooperate and negotiate with the agency. Commentors, such as former OSHA head David Michaels, are already expecting any future permanent OSHA rule to face legal challenges.²⁹ The Supreme Court's ruling in the NFIB case has given potential challengers the hope that the high court will strike down a proposed final rule, as well. Given that the legal leverage seems to be on the potential challengers' side, it would seem unlikely that they would agree to negotiate the terms of a vaccine rule.

²⁹ Emma Goldberg, *OSHA Withdraws its Workplace Vaccine Rule.*, N.Y. TIMES (Jan. 25, 2022), <https://www.nytimes.com/2022/01/25/business/osha-vaccine-mandate.html> [<https://perma.cc/E3MJ-4DER>].